

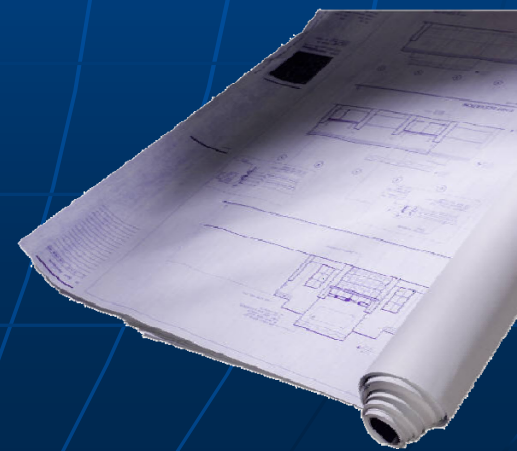
Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities

Lexington/Louisville
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Sponsored by the KYDEP

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Goals for Today's Program

- To develop a better understanding of the regulatory and environmental reasons for managing pharmaceutical waste more stringently
- To review the Ten Step Blueprint for Managing Pharmaceutical Waste
- To understand how federal hazardous waste rules impact pharmaceutical waste management in hospitals
- To consider specific state requirements Kentucky
- To explore models for implementing a pharmaceutical waste management program

Introduction to Pharmaceutical Waste

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Pop Quiz

- Is pharmaceutical waste ending up in red sharps containers in your patient care units?
- Are any unused IVs or other compounded prescriptions being disposed of down the drain?

Pop Quiz

- Are waste pharmaceuticals like warfarin and lindane, considered hazardous by EPA, being combined with non-hazardous pharmaceutical waste?
- What about items containing 24% alcohol?
- Or any items that contain mercury preservatives, such as vaccines, or eye and ear preparations?
- Are vials and IVs containing unused chemotherapy agents like Cytosan being disposed of in chemo waste containers?

Compliance – Why Now?

- US Geological Survey Studies (USGS)
- US Environmental Protection Agency (EPA)
- State Regulatory Agencies
- The Joint Commission (TJC)

USGS Water Studies



- First nationwide reconnaissance of occurrence of pharmaceuticals, hormones, other organic wastewater contaminants - March 2002
- 139 Streams in 30 states, analyzed for 95 different OWCs
- 82 of 95 detected in at least one sample
- One or more OWCs found in 80% of stream samples
- 13% of sites had more than 20 OWCs
- <http://toxics.usgs.gov/pubs/OFR-02-94/index.html>

The Faroes Statement

- 200 environmental scientists from five continents met at the Faroes Islands in the North Atlantic –May 24, 2007
- Warned of fetal exposure to toxic substances resulting in “fetal programming” to the 2nd and 3rd generation
- Lifelong effects: obesity, diabetes, cancers, ADHD, Parkinson’s, Alzheimer’s, reduced immune system
- “The dose makes the poison” replaced by “The timing makes the poison”
- New approach to testing of chemicals strongly advocated; 80% of major chemicals never tested for damage to early development
- <http://www.precaution.org/lib/rpr-html.htm>



- **5-month inquiry** discovered that drugs were detected in the drinking water supplies of 24 major metropolitan areas
- Reported that there are no sewage treatment systems engineered to remove pharmaceuticals
- Indicated drugs pose a unique danger, unlike pollutants, because they were crafted to act on the human body.
- Acknowledged continuous low-level exposure to chemo drugs, hormones, anti-depressants, antibiotics, and seizure meds found in our water could be impacting human health.

EPA Increasing Focus Pharmaceutical Waste

- EPA's Clean Water Act Review
 - Focus includes **unused or expired pharmaceutical discharges to municipal wastewater treatment plants from hospitals, long-term care facilities, and veterinarians**
- Revising the blueprint for pharmaceutical management developed by H2E and funded by the EPA
 - Scheduled for release Mid-2008
- Pressure from Congress and the public based on AP reports on drugs in the water (March, 2008)
 - Senate and House hearings possible
 - Calls for more oversight



Species at Risk



Co



LC



Effects of Chronic Exposure to Prozac

- Developmental delays
forelimb formation
tail resorption
- Increased time to
metamorphosis
- Increased mortality

Black, MC; Rogers, ED;
Henry, RB. Endocrine Effects
Of Selective Serotonin Reuptake
Inhibitors (SSRIs) on Aquatic
Organisms



Control

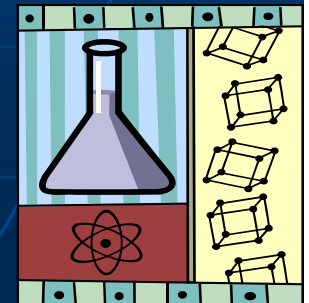
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38 ppb Prozac

Below the Dose/Response Curve: Endocrine Disruptors

- Endocrine Disruptors: chemicals that interfere with the normal function of the endocrine system (glands including thyroid, adrenals, ovaries, testicles)
- Mimic hormone, trigger identical response, block a hormone
- Do not follow the normal dose/response curve
- Active at much lower doses, especially in the fetus and newborn
- Estradiols, progesterone, testosterone
- Lindane





Playing in an Ecosystem Near You

- Lower human male sperm counts(50% reduction since 1939)
- Increased infertility
- Increased genital deformities
- Increased hormonally triggered human cancers
- Associated with neurological disorders in children
 - Hyperactivity, attention deficit
 - Lowered IQ, rage reaction
- www.ourstolenfuture.org

The Precautionary Principle

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.” Wingspread Conference, Racine, WI 1998

Applying the Precautionary Principle to Rx Waste Management

- Three aspects of Rx waste management:
 - Management of regulated hazardous pharmaceutical waste
 - Management of non-regulated hazardous pharmaceutical waste applying BMPs
 - Minimization of pharmaceutical waste
- Applying the Precautionary Principle should encourage conservative management of ALL pharmaceutical waste

Practice GreenHealth

(Formerly Hospitals for a Healthy Environment)

- Enhanced focus on hazardous waste and pharmaceutical waste
 - <http://cms.h2e-online.org/ee/hazmat/>
- EPA grant to H2E to develop a pharmaceutical waste management blueprint
 - <http://www.h2e-online.org/docs/h2epharmablueprint41506.pdf>
- EPA grant to H2E to train TJC surveyors on environmental issues



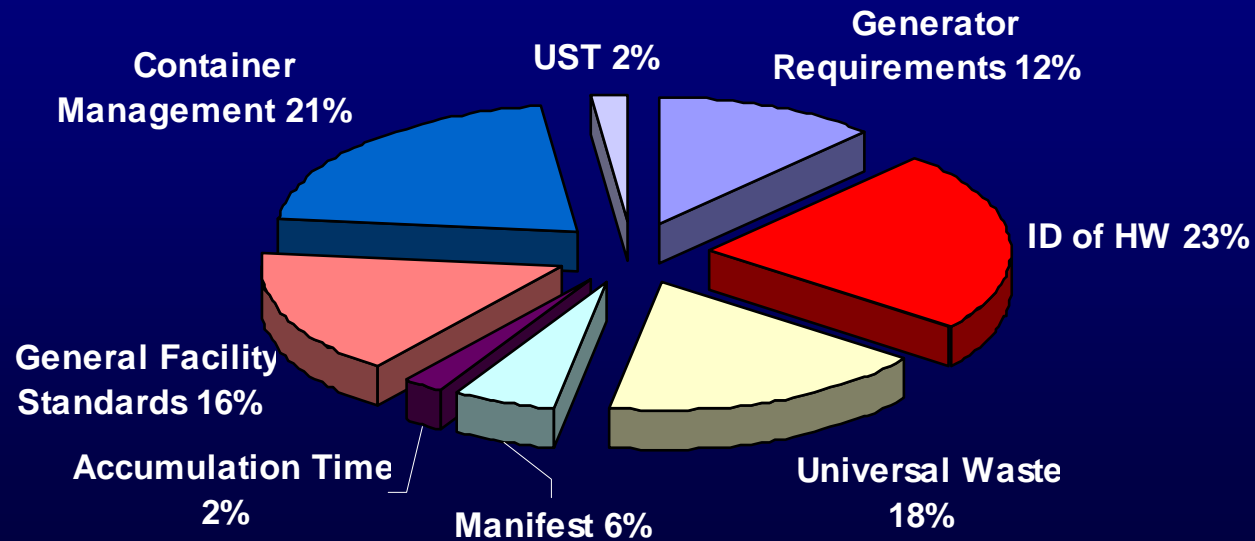
Increasing USEPA Regulatory Activity

- Region 1 (New England)
 - Veterans Administration Hospital, White River, Vermont, August 5th, 2005 cited and fined \$372,254 for hazardous waste violations

- Region 2 (NY, NJ):
 - North Shore University Hospital, Manhasset, NY fined \$40,000 (July 2003)
 - Nassau University Medical Center, East Meadow, NY fined \$279,900 (Oct. 2003)
 - Mountainside Hospital, Montclair, NJ fined \$64,349 (Nov. 2003)
 - Memorial Sloan Kettering Cancer Center, New York , NY, fined \$214,420

Healthcare RCRA Violations

Breakout of RCRA Violations from Hospital Disclosures



Slide courtesy of John Gorman, USEPA Region 2

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The Joint Commission

New Initiatives at TJC

- Adding healthcare engineers to survey teams
- Beginning to ask questions about waste disposal

Relationship to The Joint Commission Standards: Medication Management

- Standard MM.4.80
 - *Medications returned to the pharmacy are appropriately managed.*
- Elements of Performance MM.4.80
 - *3. The organization has a process in place that addresses how outside sources, if any, are used for destruction of medications.*

Relationship to The Joint Commission Standards: Environment of Care

- **Standard EC.3.10**
- *The organization manages its hazardous materials and waste^[1] risks.*

[1] Hazardous materials (HAZMAT) and waste:

Materials whose handling, use, and storage are guided or regulated by local, state, or federal regulation. Examples include OSHA's Regulations for Bloodborne Pathogens (regarding the blood, other infectious materials, contaminated items which would release blood or other infectious materials, or contaminated sharps), the Nuclear Regulatory Commission's regulations for handling and disposal of radioactive waste, management of hazardous vapors (such as glutaraldehyde, ethylene oxide, and nitrous oxide), **chemicals regulated by the EPA, Department of Transportation requirements**, and hazardous energy sources (for example, ionizing or non-ionizing radiation, lasers, microwaves, and ultrasound.)

Relationship to The Joint Commission Standards: Environment of Care

- Rationale for EC.3.10
- *Organizations must identify materials they use that need special handling and implement processes to minimize the risks of their unsafe use and **improper disposal**.*

Relationship to The Joint Commission Standards: Environment of Care

- Elements of Performance for EC.3.10
- *1. Written management plan to effectively manage hazardous materials and wastes.*
- *2. Inventory that identifies hazardous materials and waste*
- *3. Selection, handling, storage, transportation, use, and disposal of hazardous materials and waste from receipt or generation through use and/or final disposal, including managing the following:*
 - *Chemicals*
 - ***Chemotherapeutic materials***

OSHA Hazardous Drugs

- NIOSH Hazardous Drug Alert
 - Hazardous drugs as defined by OSHA/NIOSH intersect but are not the same as EPA hazardous wastes
- ASHP Guidelines on Handling Hazardous Drugs
 - Deal primarily with OSHA employee exposure issues but also refer to required or recommended hazardous pharmaceutical waste management practices

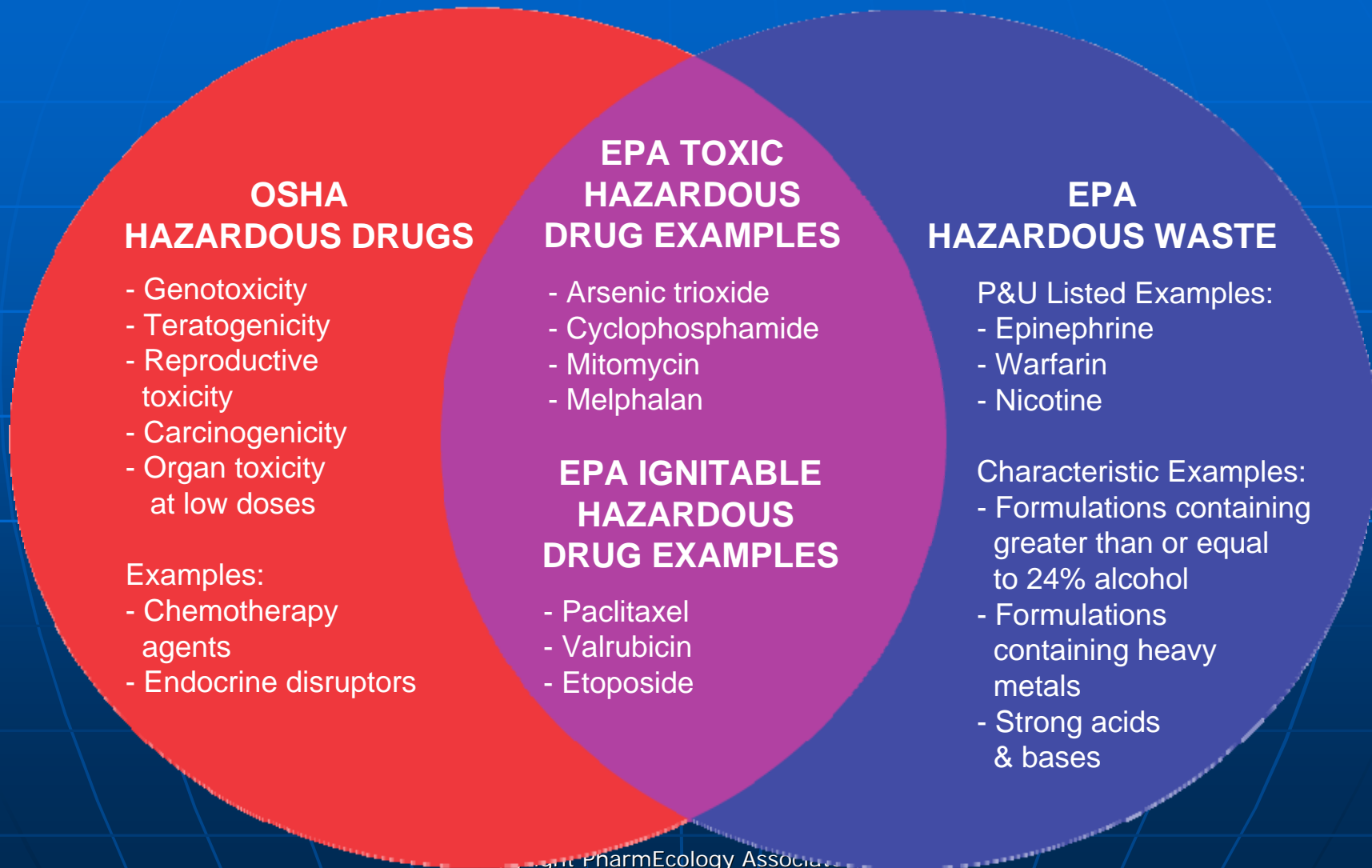


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Hazardous Drugs vs. Hazardous Waste

Where OSHA & EPA Meet



Ten Steps to Successful Implementation

- Navigating the Blueprint
- Step 1: Getting Started
- Step 2: Understanding the Regulations
- Step 3: Considering BMPs for Non-Regulated Pharmaceutical Waste
- Step 4: Performing a Drug Inventory Review
- Step 5: Minimizing Pharmaceutical Waste

Ten Steps to Successful Implementation

- Step 6: Assessing Current Practices
- Step 7: Taking On the Communication/Labeling Challenge
- Step 8: Considering the Management Options
 - Models of Implementation
- Step 9: Getting Ready for Implementation
- Step 10: Launching the Program
- Next Steps

Navigating the Blueprint

- The Ten Steps are not all consecutive. Some will occur in parallel and some will probably be referenced throughout your process.
- Due to the length and detail of the Blueprint, consider it as a reference tool.
- The primary “champions” of the process should read the Blueprint in its entirety to gain a complete picture of the process and how the steps work together.

Step One: Getting Started

- Recognition of highly interdisciplinary process
- Obtain support from senior management
- Establish a committee of stakeholders that will meet regularly
- Committee must include managers of: pharmacy, environmental services, safety, nursing, education, and infection control

Step One: Getting Started

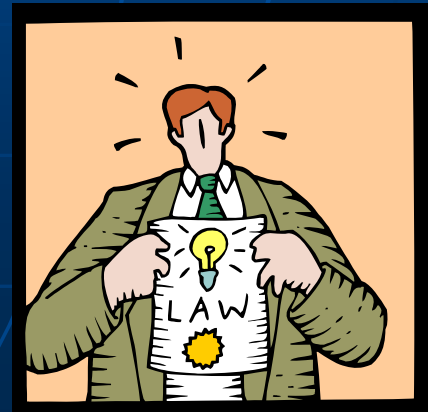
- Others to consider: Facilities/engineering, administration, laboratory, purchasing/materials management
- Recognize that increased costs involved in compliant Rx waste disposal are off-set by reduced risk of enforcement, violations, fines, TJC citations, and negative publicity

Step 2: Understanding the Regulations

- USEPA Resource Conservation and Recovery Act (RCRA)
- State environmental protection agencies may be stricter
- Defines hazardous waste for businesses in the US, including healthcare facilities

RCRA: The Defining Regulation

- Resource Conservation & Recovery Act
 - Enacted in 1976, enforced by the EPA
 - Federal regulation of the disposal of solid wastes
 - Encourages the minimization of waste generation
- Defines “hazardous waste”
- “Cradle to Grave” tracking of hazardous waste



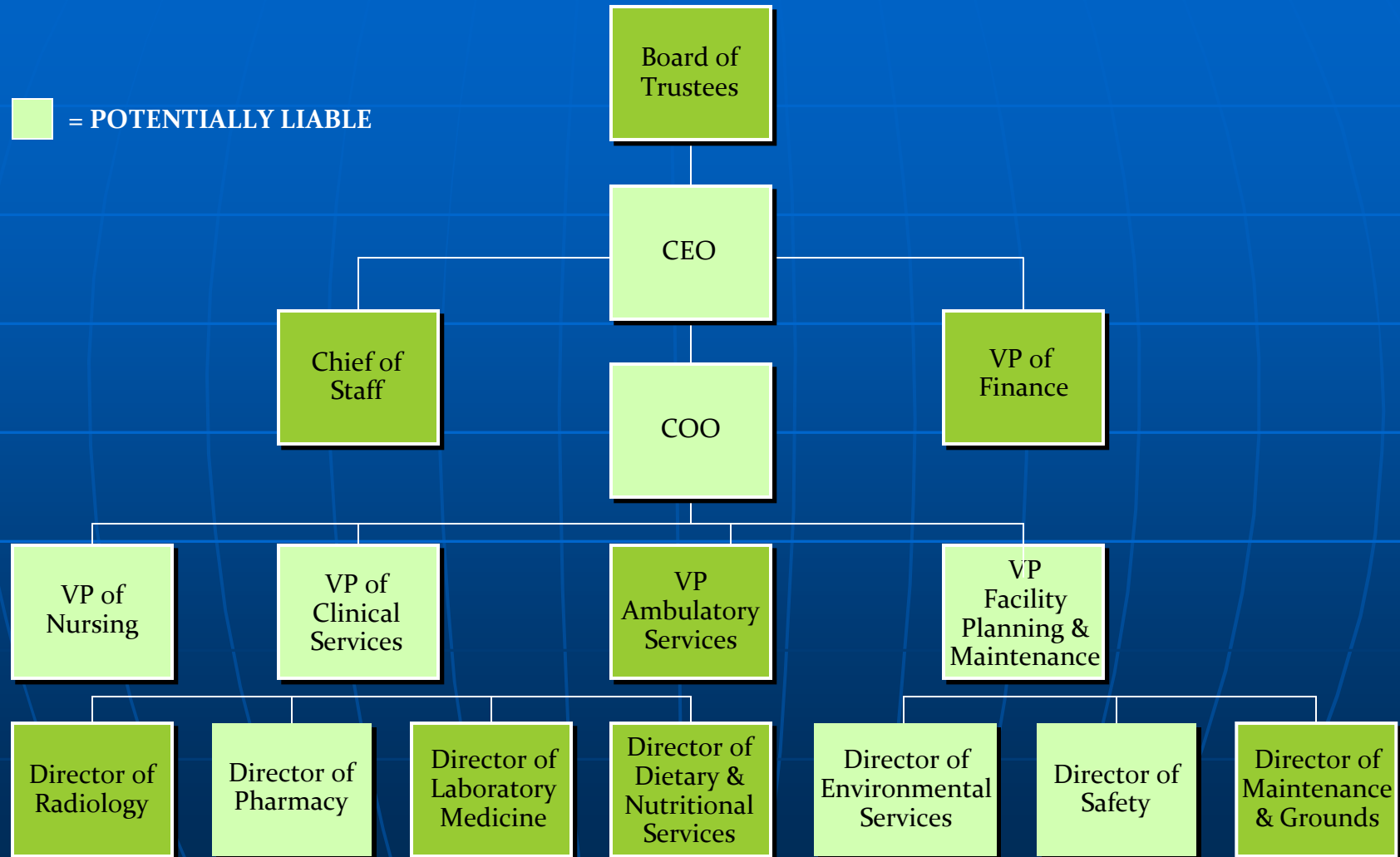
RCRA Risk Management & Liability

- Civil and criminal liability
 - Civil: State/USEPA enforcement
 - Criminal: FBI, Attorney General, Grand Jury
 - Significant environmental harm
 - Culpable conduct
- Corporate fines: Up to \$32,500 per violation/day
- Personal liability: fines and/or imprisonment
- No statute of limitations
- Managers up through CEO liable



Potential Liability for Rx Hazardous Waste Management

 = POTENTIALLY LIABLE



Criminal Case Selection Process

- Significant Environmental Harm: Factor 4

When certain illegal conduct ***appears to represent a trend or common attitude*** within the regulated community, ***criminal investigation may provide a significant deterrent effect incommensurate with its singular environmental impact.*** While the single violation being considered may have a relatively insignificant impact on human health or the environment, such violations, if multiplied by the numbers in a cross-section of the regulated community, would result in significant environmental harm.

Translation: EPA can make an example of an organization regardless of the amount of actual pollution

<http://www.epa.gov/compliance/resources/policies/criminal/exercise.pdf>

Criminal Case Selection Process

■ Culpable conduct

- Factor 1: ***History of repeated violations***
- Factor 2: Deliberate misconduct resulting in violation
- Factor 3: Concealment of misconduct or falsification of required records
- Factor 4: Tampering with monitoring or control equipment
- Factor 5: Business operation of pollution-related activities ***without a permit, license, manifest or other required documentation***

- ***EXAMPLE: If hazardous Rx waste is not being identified, segregated, and managed as hazardous waste, no manifest will exist which can be considered a repeated violation.***



Which Discarded Drugs Become Hazardous Waste?

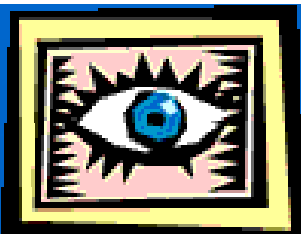
- P-listed chemicals
 - Sole active ingredient, unused
- U-listed chemicals
 - Sole active ingredient, unused
- Characteristic of hazardous waste
 - Ignitability
 - Toxicity
 - Corrosivity
 - Reactivity



Hazardous Waste Segregation Can be FUN!

- Mix and Match opportunity to apply hazardous waste information to real life simulations
- Keep an eye out for the “All Seeing Eye”
- Watch for **BOLDED ITEMS**





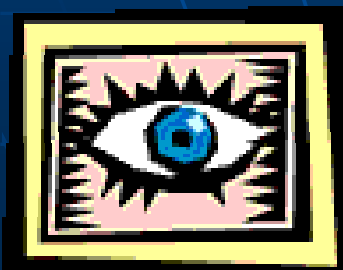
Examples of P-Listed Pharmaceutical Waste

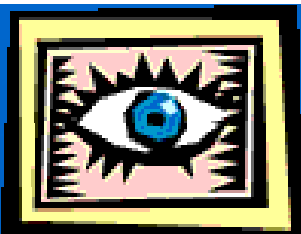
■ <i>Arsenic trioxide</i>	P012
■ Epinephrine base*	P042
■ Nicotine	P075
■ Nitroglycerin** (weak)	P081
■ Phentermine (CIV)	P046
■ Physostigmine	P204
■ Physostigmine Salicylate	P188
■ Warfarin >0.3%	P001

*Salts excluded federally as of Oct. 15th, 2007; Kentucky has accepted this position.

** Excluded from the P list federally and in Kentucky

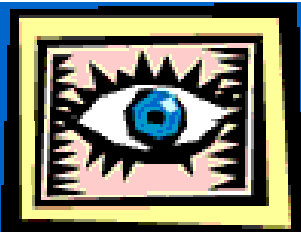
Examples of P-Listed Pharmaceuticals





Examples of U-listed Pharmaceutical Waste

■ Chloral Hydrate(CIV)	U034	■ <i>Streptozotocin</i>	U206
■ <i>Chlorambucil</i>	U035	■ Lindane	U129
■ <i>Cyclophosphamide</i>	U058	■ Saccharin	U202
■ <i>Daunomycin</i>	U059	■ Selenium Sulfide	U205
■ <i>Diethylstilbestrol</i>	U089	■ <i>Uracil Mustard</i>	U237
■ <i>Melphalan</i>	U150	■ Warfarin<0.3%	U248
■ <i>Mitomycin C</i>	U010		



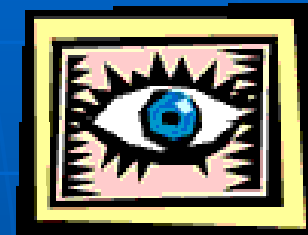
Examples of U-Listed Pharmaceuticals





Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point $<140^{\circ}\text{F}$
- Non-aqueous solutions with flash points $<140^{\circ}\text{F}$
- Oxidizers
- Flammable aerosols
- Hazardous Waste Number: D001
- Rubbing Alcohol
- Topical Preparations
- Injections





Characteristic of Corrosivity

- An aqueous solution having a pH $<$ or $=$ 2 or $>$ or $=$ to 12.5
- Examples: Primarily compounding chemicals
 - Glacial Acetic Acid
 - Sodium Hydroxide
- Hazardous waste number: D002



Characteristic of Toxicity

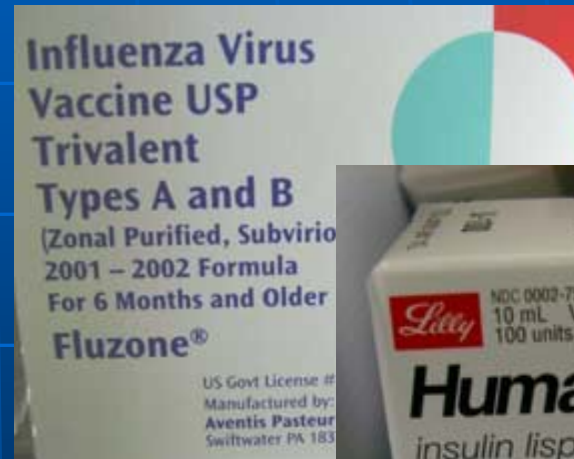
- 40 chemicals which must be below specific leaching concentrations
- Must pass the Toxicity Characteristic Leaching Procedure (TCLP)
- Must evaluate IVs, such as TPN – may come out of regulation due to dilution
- Examples of potential toxic pharmaceuticals:
 - Arsenic
 - Barium
 - Cadmium
 - Chromium
 - Lindane
 - m-Cresol
 - Mercury (thimerosal, phenylmercuric acetate)
 - Selenium
 - Silver



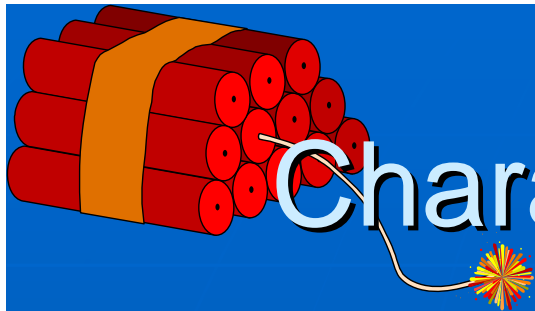
Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity



Heavy Metals: Selenium, Chromium and Silver



Preservatives: thimerosal & m-cresol



Characteristic of Reactivity

- Meet eight separate criteria identifying certain explosive and water reactive wastes
- Nitroglycerin formulations may be considered excluded federally from the P081 listing as non-reactive as of August 14, 2001, unless they exhibit another characteristics, such as ignitability.
- Kentucky has adopted the federal exclusion for nitroglycerin.
- Hazardous Waste Number for reactives: D003



Chemotherapy Agents: Many Are Not Regulated by RCRA

- About 100 chemotherapy agents not regulated by EPA
- Examples:
 - Alkylating agents: Cisplatin, Thiotepa
 - Antimetabolites: Fluorouracil, **Methotrexate**
 - Hormonal (antiandrogen): Lupron® (leuprolide)
 - Hormonal (antiestrogen): Tamoxifen
 - Mitotic Inhibitor: Taxol® (paclitaxol)



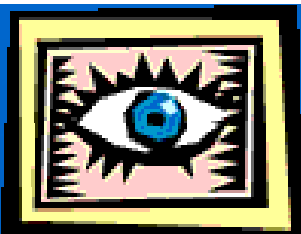
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Two Types of Chemotherapy Waste

- Trace Chemotherapy Waste (yellow)
 - Medical waste hauler protocols for “Chemo Waste”
 - Empty vials, syringes, IV’s, gowns, gloves, ziplock bags
 - Treated as infectious medical waste through regulated medical waste incineration
- “Bulk” Chemotherapy Waste (black)
 - If not empty, should be placed into Hazardous Pharmaceutical Waste container
- Spill Clean-up
 - RCRA Hazardous Waste





Definition of “Empty”

- “P” Listed Waste

Containers of “P” listed chemicals are considered hazardous waste, unless they have been rinsed three times and the rinsate discarded as hazardous waste. Never done in healthcare settings, therefore containers are also hazardous waste.

- “U” Listed and Characteristic Waste

Containers of “U” listed chemicals and characteristic wastes are empty only when

- All contents removed that can be removed through normal means
- And no more than 3% by weight remains
- Example: “Empty” Cytosan vial would be “trace” chemotherapy



What Is PharmE Hazardous[®] Waste?

- Drugs which may cause harm to human health or the environment and need to be managed according to BMPs
 - NIOSH Hazardous Drug Alert Appendix A
 - The US Department of Health and Human Services National Toxicology Program's Report on Carcinogens (11th Edition)
 - Drugs with LD50s at or below 50mg/kg
 - Endocrine disruptors
- Identified as PharmE Hazardous[®] in Inventory Analysis
- BMP recommendation is to segregate at least chemo agents into RCRA toxic hazardous waste containers and to dispose of other agents through incineration

Hazardous Waste Incinerators

- Permitted by USEPA, known as a Treatment, Storage and Disposal Facility (TSDF)
- High temperature, molecular bonds broken
- Pollutants scrubbed, emits only water vapor, ash stored in a lined, hazardous waste landfill
- Authorized to accept the “worst of the worst” hazardous chemicals, shipped on a 5-part manifest
- Examples:
 - Veolia
 - Clean Harbors
 - Heritage

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How Should Non-hazardous Drugs be Handled, Stored and Disposed?

- BMPs strongly discourage sewerage and landfilling of non-hazardous drugs
- Organization can minimize risks by adopting BMPs
- Possible exception: controlled substances due to difficulty in rendering non-recoverable under Drug Enforcement Administration (DEA) regulations
- Consider segregating into white container with blue top (used extensively in California)
- Label "Incinerate Only"
- Dispose at a regulated medical waste incinerator or municipal incinerator that is permitted to accept non-hazardous pharmaceutical waste



Municipal and Regulated Medical Waste Incinerators

- Municipal Incinerator
 - Permitted to burn municipal “garbage”
 - Usually not permitted to handle infectious waste
 - May be permitted to handle non-hazardous pharmaceuticals, with certain volume restrictions
- Regulated Medical Waste Incinerator
 - Permitted by USEPA and the state to accept pathology waste, red bag and red sharps waste, trace chemo waste
 - May be permitted to accept non-hazardous pharmaceutical waste
 - Regulated under the Clean Air Act
 - Lower temperature, less controls than TSDF
 - Ash disposed of in a municipal (non-hazardous) landfill; may or may not be lined



Common But Inappropriate Pharmaceutical Waste Stream Management

Type of Waste Container	Color code	Contents	Treatment Method
Red bag (non-pathology)	Red	Biohazardous (RMW) + Rx	Autoclave/ Landfill
Red sharps/ needlebox	Red	Biohazardous; needles, etc. + Rx	Autoclave/ Landfill
Trace chemo Rx	Yellow or White	Bulk & Trace Chemo	RMW Incineration
Sewer		Unused IVs, tablets, etc.	Wastewater Treatment Plant
Municipal Trash		Unused ointments, inhalers, etc	Landfill



Pharmaceutical Waste Management Recommendations

Type of Waste Container	Color code	Contents	Treatment Method
Red bag (non-pathology)	Red	Biohazardous (RMW) No Rx	Autoclave/ Landfill
Red sharps/ needlebox	Red	Biohazardous; needles, No Rx	Autoclave/ Landfill
Trace chemo Rx	Yellow or White	Biohazardous & Trace Chemo	RMW/ Incineration
RCRA Toxic Hazardous Rx	Blue or Black	RCRA, bulk chemo, & BMP Hazardous Rx	RCRA TSDF
RCRA Ignitable Hazardous Rx	Blue or Black	RCRA ignitable Hazardous Rx	RCRA TSDF
Non-hazardous Rx Waste	White/Blue or Purple top	Non-hazardous Rx waste	Municipal/RMW Incineration

Step 4: Performing a Drug Inventory Review

- Perform initial inventory review
 - Obtain drug specific data from purchasing records
 - Identify ingredients
 - Determine RCRA hazardous waste code
 - Make Best Management Practice determinations
- Document decision making process
- Keep the review current

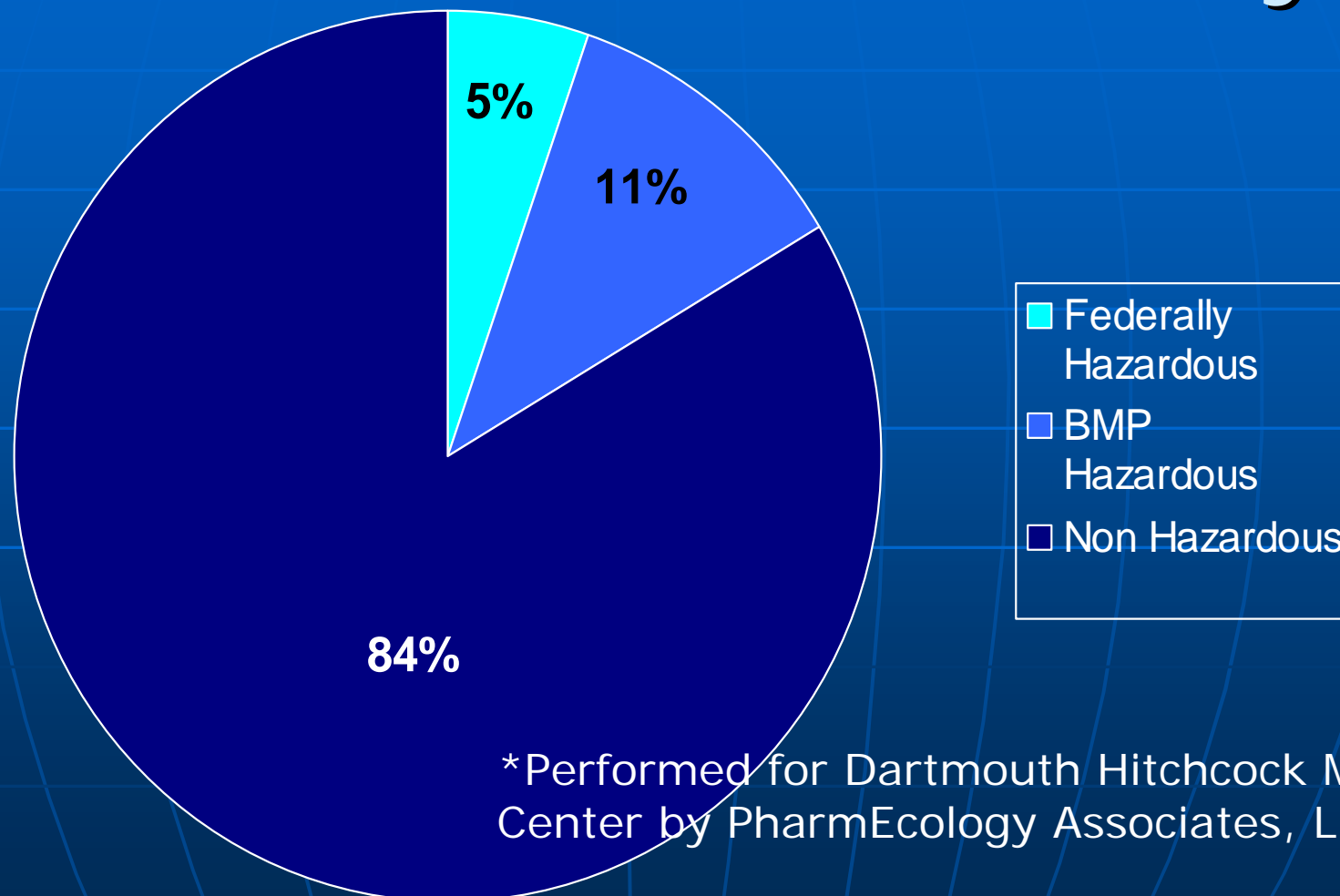
Reformulations and Compounded Items

- Hazardous waste designation for reformulations and compounded items may not be the same as for original formulation
 - Paclitaxel contains ~ 50% alcohol in original vial
 - Manage residue in vial as ignitable hazardous waste
 - Alcohol < 24% when diluted in IV
 - Apply BMP and discard unused IV as “bulk” chemotherapy hazardous waste

Managing Specialty Wastes

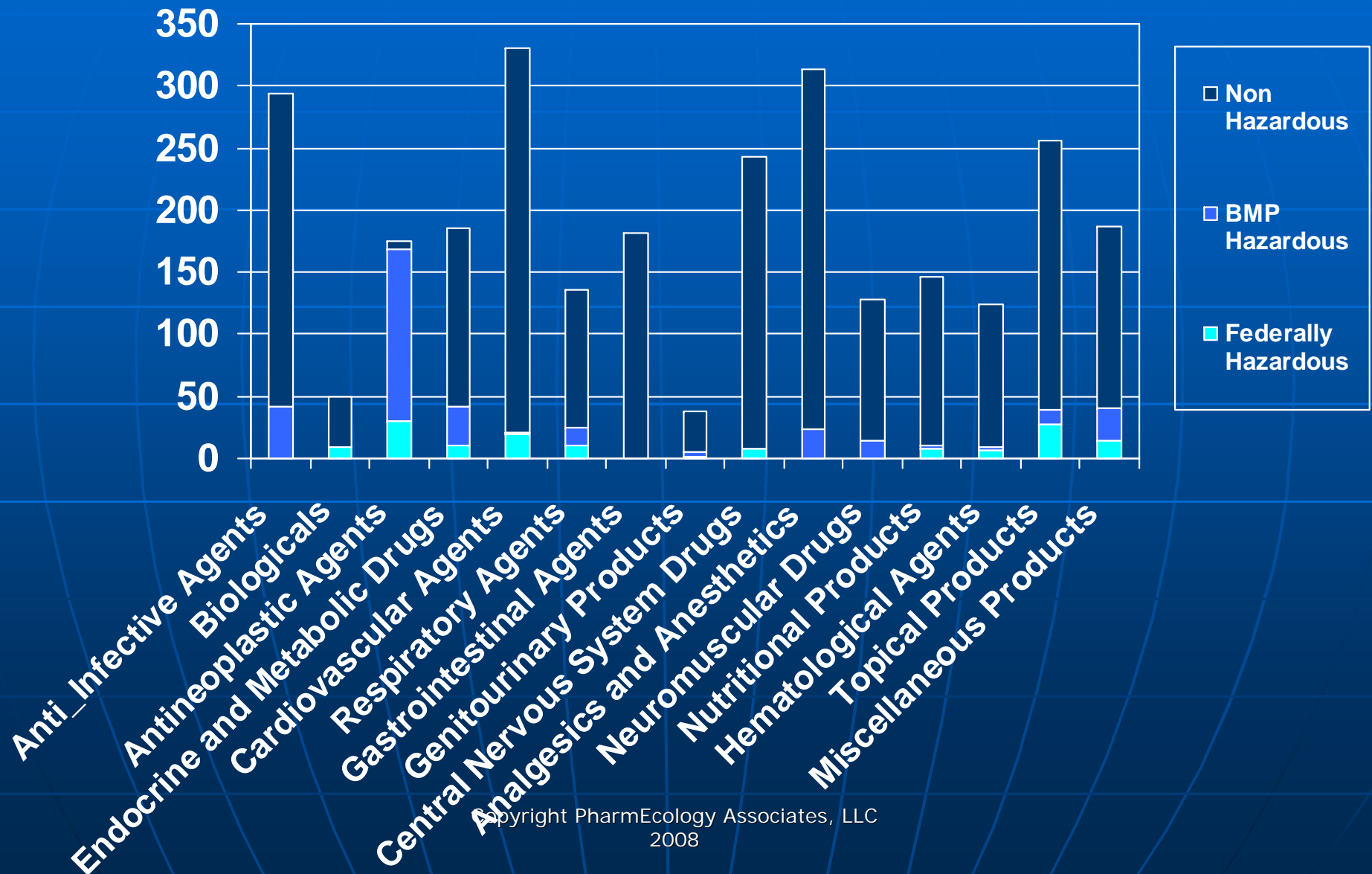
- Controlled substances:
 - May be handled by some hazardous waste vendors as a transfer between DEA registrants
 - Can be shipped to a reverse distributor as a transfer between registrants (non-hazardous waste)
 - Sewering still the most economical until a system for rendering the controlled substances non-recoverable can be developed
- Hazardous/RMW wastes:
 - Some hazardous waste vendors can accept dual hazardous and infectious waste

DHMC Waste Characterization Summary*



*Performed for Dartmouth Hitchcock Medical Center by PharmEcology Associates, LLC

DHMC Inventory Review








DHMC Frequency Analysis

Drug	Waste Code	Units				
Arsenic Trioxide	P012	HSCU	Neuro			
Epinephrine	P042	ED	CCU	ICU	CTIC	ICCU
Chloral Hydrate	U034	Psych Care	PICU	Psych Med		
Oxymetazoline Nasal Spray	D009 (Hg Preservative)	Med/ Surg.	ED			

Sample Guidance Poster

Proper Waste Disposal in Hematology/Oncology

				
Infectious Waste: Red Bucket w/Tan Bag	Trace Chemo and Combined Chemo/Infectious: Yellow Bucket	EPA-Regulated Chemo Waste: Blue Bucket	Ordinary Trash: Clear Bag	Sharps: Sharps Container
<ul style="list-style-type: none"> Materials not exposed to chemo but saturated with blood or body fluids (i.e., could get at least a drop out by squeezing or flicking). Containers of blood products or other potentially infectious materials. <p><i>Absorbent materials not saturated with blood should be disposed as ordinary trash.</i></p>	<ul style="list-style-type: none"> EMPTY* chemo containers (IV bags, tubing, vials, syringes, ziplock bags). IV sets that have held chemo and remain attached to catheter or other bloody material. Gloves, gowns, ziplock bags, other paraphernalia used to administer chemo but NOT VISIBLY CONTAMINATED with chemo (i.e., no known droplet or spill). Linens containing urine or feces of chemo patients. 	<ul style="list-style-type: none"> Chemo containers that are NOT EMPTY* and have NO CATHETER attached. Paraphernalia (e.g., gloves, gowns) that HAVE BEEN VISIBLY CONTAMINATED with chemo. Materials used to clean up a chemo spill. All arsenic trioxide sets (separate from port; dispose port in yellow). 	<ul style="list-style-type: none"> Materials not exposed to chemo and not saturated with blood or body fluids (i.e., could not get a drop out by squeezing or flicking). Examples: non-chemo IV bags, packaging, food waste. 	<ul style="list-style-type: none"> All sharp objects that have not been exposed to chemo.
Autoclaved on premises & landfilled	Sent to medical waste incinerator	Sent to hazardous waste incinerator	Sent to municipal landfill	Ground, microwaved, and landfilled; container is cleaned and reused

*Empty = Less than 3% of contents remaining

Capturing New Drugs

- Establish systems to:
 - Capture new drugs added to the formulary and non-formulary purchases at least quarterly
 - Manage discarded physicians' samples
 - Discard personal medication left by patients appropriately
- PharmE® Waste Wizard used in study
 - Online search engine
 - Over 170,000 drug products updated weekly

Public Access to Resources and FAQs at www.pharmecology.com

http://www.pharmecology.com - PharmEcology - Microsoft Internet Explorer

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*Establishing
**compliant and
cost-effective
procedures
to manage
pharmaceutical
waste.***

Pharm@® Inventory Analysis
Get started by identifying your hazardous waste pharmaceuticals

Pharm@® Waste Wizard
Keep up-to-date on-line with our weekly database updates

Over 300 New Products Each Week

■ 3 - Federally Hazardous
■ 2 - PharmE Hazardous
■ 1 - Non Hazardous

Pharm@® On-Site Risk Assessment
Find out how your current pharmaceutical waste management practices can be improved

Pharm@® Policies and Procedures
Use our EPA Resource Conservation and Recovery Act (RCRA) compliant templates to upgrade your policies and procedures

News Alert: PharmEcology Revises Status of EPI and Nitro in the PharmE® Waste Wizard

Internet



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Providing Environmental Consultation to the Healthcare Industry™

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Welcome : Elayne Dudley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN



Change State



Change Password



What Products are in
the Database?



How Does the Search
Logic Work?



What Is "PharmE
Hazardous™ Waste"?



Product Questions?
Contact Us



Logout

Individual Product Search

Batch Product Search

PharmEcology Admin

Search By NDC Number

NEW SEARCH

NDC number:

0182267101

(For example: 1234045610 or 1234-456-10 or 1234-456)

Search by Product Name

Product name:

Strength (optional):

Search by Generic Name or Active Ingredient

Generic name:

Manufacturer (optional):

Strength (optional):

*Hints

SEARCH >>

1. Enter a full or partial NDC number, with or without hyphens
2. Enter a full or partial product or generic name
3. Enter the beginning of the strength, ignoring the concentration or additional ingredients



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Pharm@ecology Associates, LLC
Providing Environmental Consultation to the Healthcare Industry™

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Welcome : Elayne Dudley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN

Federal Hazardous Waste
PharmE Hazardous™ Waste
Non-Hazardous Waste

What Products are in the Database?
How Does the Search Logic Work?
What Is "PharmE Hazardous™ Waste"?
Product Questions? Contact Us
Logout

Individual Product Search Additional Information

Federal Hazardous Waste NEW SEARCH

Product: 00182-2671-01 WARFARIN TAB 1MG 100.00 EA Rx
Generic: Warfarin Sodium DEA: Non-Controlled
Manufacturer: GOLDLINE

Recommended Waste Classification

Regulated as federal hazardous waste:
P001-Warfarin (conc. greater 0.3%)

Recommended Waste Stream

Handle as hazardous waste:
Toxic

Highlights

200 South Executive Drive, Suite 101 • Brookfield, Wisconsin 53005 • TEL: 262.814.2635 • FAX: 414.479.9941 • info@pharmecology.com

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Federal Hazardous Waste NEW SEARCH

Product: 00182-2671-01 WARFARIN TAB 1MG 100.00 EA Rx
Full name: WARFARIN SODIUM 1.00 MG
Reference: eFACTS (Facts & Comparisons Online)
Page: Warfarin Sodium

WARFARIN

Warfarin is defined by USEPA as a P-listed, acutely hazardous waste when present as the sole active ingredient in concentrations greater than 0.3% (P001). All manufactured dosage forms exceed the 0.3% criteria.

All containers that have held P-listed waste must be managed as hazardous waste unless triple rinsed. If triple rinsed, all rinsate must also be treated as hazardous waste. The rinsed RCRA-empty container may then be disposed of as non-hazardous waste.

If present as the sole active ingredient in concentrations equal to or less than 0.3%, warfarin is a U- listed hazardous waste (U248).

For additional information, refer to:
<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=3814ba269b3466ca3675c45c3e6956f6&rgn=div8&view=text&node=40:25.0.1.1.2>

Regulation Summary For: WISCONSIN

Internet

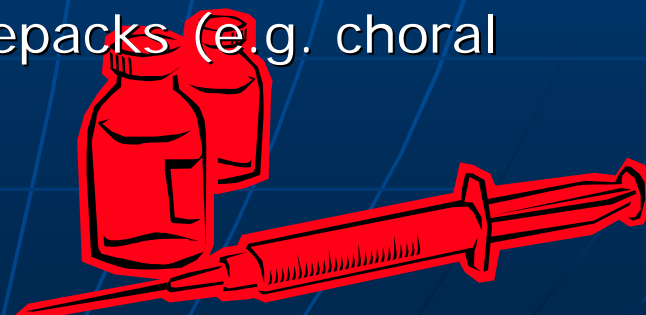
Step 5: Minimizing Pharmaceutical Waste

- Limitations on less hazardous drug substitution
 - Hazardous nature of drug often provides therapeutic effect
- Always ask:
 - What pharmaceuticals are being wasted?
 - Why are they being wasted?
 - How can wasting be minimized?



How Can Hazardous RX Waste Generation Be Minimized?

- Inherent limitations on substitution of a less hazardous drug since the hazardous nature of the chemical often provides the therapeutic effect
- Tighter inventory control to reduce outdate generation, both original manufacturers' containers and repacks
- Pre-labeling of multi-dose items such as ointments, inhalers, as take-home meds – works best in smaller, primary care hospitals
- Single dose vials vs. multiple dose vials
- Patient specific oral syringes vs. 10 cc. repacks (e.g. choral hydrate for pediatric use)



Step 6: Assessing Current Practices

- Performing department reviews
 - Quantitative volumes/weights of discarded drugs difficult to obtain
 - Informal but well documented interview process in pharmacy and nursing units can determine current medication disposal practices
- Schedule units in advance
 - Emphasize “no wrong answer” approach
- Utilize data from automated dispensing machines
- Conduct a frequency analysis, especially for drugs which become hazardous waste



Federal Hazardous Waste Generator Status

- Large Quantity Generator (LQG): generates more than 1000 kg/month of hazardous waste or **>1 kg/month "P" listed waste.**
- Small Quantity Generator (SQG): Generates <1000 kg/month but >100 kg/month of hazardous waste & < or = 1 kg/month "P" listed waste.
- Conditionally Exempt Small Quantity Generator (CESQG) : Generates < or = 100 kg haz waste/month, < or = 1kg P listed waste/month

Documenting Your Hazardous Waste Generator Status

- Large quantity generator: no need to record P waste separately.
- Small or very small quantity generator: need to segregate all P-listed including empty containers and document weights per calendar month
- Cannot exceed 1 kg or 2.2 lbs/month for any given month

Step 7: Taking On the Communication/Labeling Challenge

- Determine an acceptable label that indicates the item is a toxic or ignitable hazardous waste
 - Special Disposal Required
 - HW-T (for toxic)
 - HW – T Full or Empty (for P-listed waste)
 - HW-I (for ignitable)

Labeling in the Pharmacy and Nursing Units

- Shelf-stickers in the pharmacy
- Automating the labeling process for nursing units
 - Incorporating disposition data into dispensing software
 - Must include all possible labeling scenarios: unit dosed items, IV admixtures, re-formulated items, robot dispensed labels
 - Inserting disposition data on barcodes
 - Must be bedside barcode enabled
- Manually labeling in the pharmacy for nursing units

Step 8: Considering the Management Options

- Model I: Segregating at the Point of Generation
 - Option A: Automatic Sorting Device
 - In beta testing
 - Option B: Data Applied to Dispensing Software
 - Option C: Stickers Applied Manually
- Model II: Centralizing Segregation
- Model III: Managing All Drug Waste As Hazardous

Model I Option A: Automatic Sorting Device

- Vestara's EcoRex®
 - Proprietary database of 170,000+ NDCs
 - Integrated IT network
 - Omni-directional barcode scanner
 - Cart and wall configuration
 - Tamper-proof reusable containers
 - Scan, dispose and close



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Pros and Cons

Pros:

- Lower training costs
- One-time inventory analysis
- Reduction in human error
- Automatically updated weekly
- Locked stations located anywhere

Cons:

- Pharmacy must be bar-code enabled
- Equipment must be acquired

Model I Option B: Data Applied to Dispensing Label Software

- Entire inventory is analyzed
- Shelf stickers in pharmacy
- Data is entered into the dispensing software at the NDC or “pneumonic” level
- Label prints with pre-determined code
 - HW1, RCRA1, Black Bin, etc.
- Nursing staff are trained on waste segregation based on codes
- Black “satellite accumulation” containers in soiled utility rooms; restricted entry black containers in patient rooms
- Hybrid Model: North Memorial Health Care
 - Programmed automated dispensing machines (e.g., Pyxis)



Pros and Cons

Pros:

- Eliminates manual stickering of dispensed items
- Reduces opportunity for human error

Cons:

- Must have dispensing software that is flexible and can accept message
- Must still sticker pharmacy shelves to alert pharmacy staff
- Printed message may not show up as well as stickers
- System must be maintained by pharmacy staff

Model I Option C: Manual Labeling of Hazardous Waste

- Entire inventory is analyzed
- Shelf stickers are applied
- Items are stickered upon dispensing
- Nursing staff are trained on waste segregation based on stickers
- Black "satellite accumulation" containers in soiled utility rooms
- Model program: North Memorial Health Care
 - http://www.hospitalconnect.com/hfmmagazine/jsp/articleDisplay.jsp?dcrpath=HFMMAGAZINE/PubsNewsArticleGen/data/2006March/0603HFM_DEPT_EnvirSer&domain=HFMMAGAZINE

North Memorial Health Care Robbinsdale, MN

**SPECIAL DISPOSAL
REQUIRED**



ciates, LLC
Photos courtesy of
North Memorial Health Care

Pros & Cons

Pros:

- Relatively easy to implement regardless of software
- No programming costs

Cons:

- Labor intensive and relies on consistent employee performance
- Higher training costs
- System must be maintained by pharmacy staff

Model II: Centralizing Segregation

- All pharmaceutical waste is collected in hazardous waste containers in the pharmacy and in the nursing units
- The mixed waste is removed to the central hazardous waste storage accumulation area
- Sorting is done by hazardous waste vendor or trained hospital staff based on an analysis of the inventory
- Hazardous waste and related items are manifested and disposed as such
- Model: Abbott Northwestern Hospital

Abbott Northwestern Hospital Minneapolis, MN



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Pros & Cons

Pros:

- No time spent in pharmacy on stickering or maintaining software system
- Less time spent on training pharmacy and nursing personnel on segregation rules
- Less chance of error based on expertise of vendor

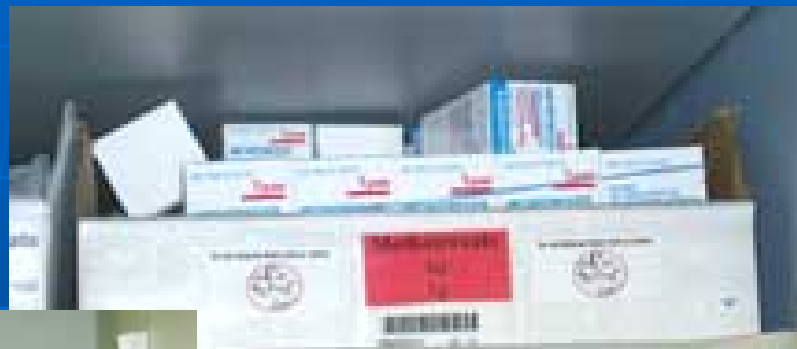
Cons:

- Still must analyze inventory and keep up-to-date with new items
- Increased cost of vendor for sorting time

Option III: Managing All Pharmaceutical Waste as Hazardous

- Easiest, most expensive
- May still need to sort out aerosols
- Still need to do analysis of inventory to determine waste codes for manifesting
- Hybrid Model: UW Health, Madison, WI
 - All tablets/capsules/solids hazardous
 - IVs hazardous if RCRA, PharmE HazardousTM (BMP)

UW Health Madison, WI



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Step 9: Getting Ready for Implementation

- Locating your satellite accumulation areas
 - Pharmacy
 - Clean rooms and all pharmacy dispensing areas
 - Nursing units
 - Soiled utility rooms
 - Patient rooms if restricted entry container used

Satellite Accumulation Requirements

- Label each container as "Hazardous Waste" with the appropriate waste stream noted
- No time limit to fill the container
- No more than 55 gallons of U listed and characteristic waste or 1 quart of P listed waste may be accumulated
- Must be moved to storage accumulation within three days after these quantities are reached

Tips for Satellite Accumulation

- Keep wastes in their original closed container
 - Do not squirt or drain liquids into the satellite container
 - Do not empty tablets or capsules into the satellite container

- If P waste escapes into the container, the entire container becomes contaminated P-listed waste

Evaluating Your Storage Accumulation Area

- Provides a safe and secure storage area for hazardous waste while it awaits shipping
- Same locked area as for xylene, formaldehyde, lab chemicals
- Maximum storage time: 90 or 180 days based on generator status
- May need a larger area or more frequent vendor pick-ups

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Selecting the Right Vendor(s)

- For RCRA hazardous waste, vendor must be permitted by EPA as a treatment, storage and disposal facility (TSDF)
 - Request a copy of their notification
- Insure your current vendor can handle all new waste codes
 - Provide them with all P, U and D codes
- Ask for a waste profile to be generated to enable manifesting without documenting each item in each container
 - KY may require all waste codes to be listed on the container
- Ask if vendor can pre-certify the items and combine ignitables with toxics to simplify waste segregation
- Determine if you will have special needs, such as hazardous controlled substances or mixed hazardous/regulated medical waste streams

Reverse Distributors Are NOT Waste Management Services

- Most reverse distributors are generators of hazardous waste, not TSDFs
 - Not permitted to accept hazardous waste
 - May not be permitted to accept ANY waste
- Two letters to the industry from EPA specifically state that reverse distribution is NOT to be used as a waste management system
 - Don't push the system
 - Send only potentially creditable outdated drugs to RDs
 - Kentucky requires that credit be given for the outdates – if not creditable, manage as waste at the facility

Conducting a Pilot Program

- Pilot the program in the pharmacy first
 - Requires shelf stickers on drugs that become hazardous waste
 - Introduces concept to pharmacy staff
- Consider inpatient and/or outpatient oncology
- Find nursing “champions” within the system

Develop Policies and Procedures

- Complete pilots to determine best methods to use
- Develop policies and procedures applicable to the entire facility
 - Be sure to involve all stakeholders
- Consider developing a pharmaceutical waste flow chart and/or pictorial diagrams for each area
- Be sure to update spill management plans to include non-chemo hazardous waste

Step 10: Launching the Program

- Educating and training staff
 - Notify the entire facility of the timetable for training and roll out
 - Train all shifts immediately before their units/department is to begin waste segregation
 - Stick with the timetable!
- Take advantage of Safety Fairs, Nursing Education Expos, or other hospital-wide events for a general introduction
- Involve nursing educators initially, with new hires, and for annual training

Hazardous Waste Manifests and Land Disposal Restriction Forms

■ Hazardous Waste Manifests

- Highly technical
- Involve your hazardous waste vendor
- Certification of all P, U and D codes simplifies the process
- Universal Manifest required in September, 2006

■ Land Disposal Restriction Forms

- Indicates what wastes you are disposing and how they will be treated prior to land application
- Hazardous waste requires high temperature incineration
- Hazardous waste vendor should complete for you

Tracking, Measuring and Recording Progress

- Hazardous waste identification: document your process initially and how new drugs are evaluated
- Labeling: document consistency, especially with manual processes; re-evaluate processes annually
- Compliance: perform periodic surveys to determine if procedures are understood and followed
- Quantity: track the number, size, weight of hazardous waste containers generated
- Costs: track all costs involved
- JCAHO Performance Improvement Initiative: Document for next survey and H2E Award Opportunity: Identify goals and action plans; submit your efforts for annual recognition

Best Management Practices: Managing to the Highest Standard

- Hazardous waste regulations have not kept pace with drug development
- Approximately 10% of the drugs that are not regulated are equally as hazardous
- Best management practices encourage managing drugs that are equally harmful as hazardous waste when discarded
- Best management practices also discourage sewerage and landfilling of all drugs



Next Steps

- This Blueprint should be viewed as a beginning to addressing an emerging issue, not an end in itself
- A great deal of national dialog needs to occur to determine the optimum management of waste pharmaceuticals, including household waste generation
- You as healthcare leaders will be creating the optimum solutions of the future



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